EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-31

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2016 Base Option Period Number 2	Epidemiologic Support for IRIS

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	A.1,2; B.1,2,3,4,5; C.1; D; and G.1,2

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2015 To 10/31/2016

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 11/01/2013 To 10/31/2016 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee: — LOE:

Cumulative Approved: — Cost/Fee: — LOE:

Work Assignment Manager Name: Amanda Persad (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 919-541-9781	
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Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 703-347-8523	
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Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 513-487-2852	
	FAX Number: 513-487-2107	

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 2-31

TITLE: Epidemiologic Support for IRIS

Principal Section & Paragraph of SOW: A.1,2; B.1,2,3,4,5; C.1; D; and G.1,2

PERIOD OF PERFORMANCE: November 1, 2015 – October 31, 2016

I. PURPOSE

This work assignment is a follow-on to work performed under Work Assignment 0-31 and 1-31. The purpose of this work assignment is to provide continued services to the U.S. Environmental Protection Agency's (hereinafter, EPA) National Center for Environmental Assessment (NCEA), within the Office of Research and Development (ORD). The specific purpose is to provide expert epidemiologic support for the development of Integrated Risk Information System (IRIS) scientific materials, including both qualitative and quantitative analyses and syntheses of human data and exposure information as identified in the contract performance work statement, Sections A(1 and 2); B(1,2,3,4 and 5); C (1); D and G (1 and 2) .

II. BACKGROUND

EPA's Integrated Risk Information System (IRIS) is a human health assessment program that evaluates quantitative and qualitative risk information on health effects that may result from exposure to environmental contaminants. When supported by available data, IRIS provides oral reference doses (RfDs) and inhalation reference concentrations (RfCs) for chronic non-cancer health effects, and oral slope factors and inhalation unit risks for carcinogenic effects. IRIS contains chemical-specific summaries of qualitative and quantitative health information in support of two steps of the risk assessment process, i.e., hazard identification and dose-response evaluation. By combining IRIS toxicity values with specific exposure information, government and other entities use IRIS to help characterize public health risks of chemical substances and thereby support risk management decisions designed to protect public health.

The IRIS Program is currently developing the 2016 IRIS agenda. The draft list of chemicals anticipated to appear on the agenda is provided in Appendix A. Assessments for some of these chemicals are in progress and others will be initiated in the coming fiscal years. In response to the evolving needs of EPA's Program Offices and Regions and IRIS Program resources, additional chemicals may be added to the agenda, and some chemicals may be dropped. Scheduling of chemical assessments will depend on a number of factors, including regulatory/ programmatic priorities, availability of staff and other resources, and potential public health impact of an assessment. Therefore, the IRIS Program will need to preserve flexibility in determining which assessments, whether the chemical is listed in Appendix A at this time or not, will require assistance during the period of performance of this Performance Work Statement (PWS).

III. SCOPE OF WORK: TASKS AND DELIVERABLES

Requirements Specific to this Work Assignment

Under this WA, an episode of work (aka "request") shall be initiated by written Technical Direction (TD). Each request will clarify deadlines for delivering drafts and final work products. An initiating TD will identify the data and the specific Tasks (as outlined below) to be performed.

The Contractor shall prepare documents in the format specified in the current IRIS standard operating procedures and templates (to be provided by EPA). Recent examples of final and draft assessments for other chemicals may also serve as models. Documents shall be technically edited for format and grammar before being delivered to the EPA Work Assignment Manager (WAM).

The Contractor shall be given an account in HERO (Health and Environmental Research Online), with access to scientific literature. Copyright law of the U.S. (Title 17 U.S. Code) governs the making of reproductions of copyrighted material. Section 107 of the copyright act instructs that, "the fair use of a copyrighted work for purposes such as ... research, is not an infringement of copyright." The Contractor is liable for any infringement of copyright. To set up the HERO account, the Contractor shall send an email to hero@epa.gov - and include the following information: Names, addresses, phone numbers, emails of all contractors needing HERO accounts, project name, start date and end date. The contractors will receive their HERO account information, with user documentation, within 3 business days.

HERO shall be used for performing literature searches. The literature search shall include, at a minimum, the following databases: PubMed, Web of Science, ToxNet; but may include others, as appropriate. The results from the literature search shall be submitted to HERO, as described in the user documentation. EPA will provide the PDFs through the HERO interface.

The Contractor shall use HERO (Health and Environmental Research Online) for reference citation and bibliographic generation, as described in the user documentation.

The Contactor shall develop and maintain internal documentation and data pertaining to all assumptions, data sources, databases, procedures, statistical analyses, and computer programming code, scripts, and software instructions used to support and execute EPA's requirements and deliverables, in order that results can be replicated. The contactor will provide access to this internal documentation upon request by the EPA WAM or EPA Project Officer.

The Quality Assurance Project Plan (QAPP) developed under WA 0-31 during the Base Period will be used for this work assignment. The funding or scope of work is not expected to change for this WA. A kick-off conference call has been completed under WA 0-31 and thus is not required for this WA.

Task 1: Develop a Work Plan

The Contractor shall prepare a written work plan proposing a technical approach to the work assignment. The work plan shall outline how the work shall be performed and provide a list of deliverables and interim deliverables with the schedule for completion. In addition, the budget and staffing plan and a brief description of the qualifications of the key technical staff shall be included. The Contractor shall maintain communication with the WAM through weekly phone calls or email updates.

Deliverable Schedule: Work plan due in accordance with the contract.

Task 2: Quality Assurance Project Plan (QAPP) [completed in Base Period]

Task 3. Kick-off Conference Call [completed in Base Period]

Task 4: Manage, Identify and Recruit Expert Epidemiologists

The Contractor shall identify, recruit and manage expert epidemiologists ("experts") to develop sections of IRIS Toxicological Reviews and/or related materials. The Contractor shall be responsible for ensuring timely communication is passed between the EPA work assignment manager (WAM) and the experts so that technical clarification can be offered and interaction between EPA and the experts can occur as needed. The Contractor shall also ensure that the deliverables are provided to the EPA WAM in a timely manner.

EPA seeks to identify and recruit experts to develop several document sections/types for several different chemical assessments. These sections are discussed further in Task 5 within this WA, and they include:

1) Evaluation of exposure methods in epidemiological studies;

2) Study methods evaluations;

3) Evidence tables of specific health effects;

4) Graphical displays of evidence of specific health effects;

5) Other epidemiologic support (quantitative analysis, expert opinion, white papers, etc.).

EPA will provide guidance for the development of evidence tables and templates of the evidence and summary tables. The chemical assessments and related documents that will require assistance under this PWS will be clarified through technical direction.

The EPA assumes primary authorship in the writing process for all materials and contributing experts are listed in the final documents as appropriate. EPA will approve each of the experts performing work within two days of notification of a potential candidate.

Subtasks

1) **Identify and Recruit Expert Epidemiologists**

The Contractor shall identify and contact experts with a knowledge base that is aligned with the descriptions in each written TD. Each TD will specify the minimum/desired qualifications of the experts for that chemical assessment. The expertise needed will be specific to the broad field of epidemiology. Approximately 6-10 experts will be needed. Potential experts shall be asked to submit a bio-sketch to ensure they meet the minimum/desired qualifications, and EPA will notify the contractor of its concurrence with the selection.

2)

3) Manage Expert Epidemiologists

The Contractor shall manage the recruited experts and ensure timely communication occurs between EPA and the experts. This shall involve setting up conference calls with the experts and EPA staff. In addition, the Contractor shall ensure that the written sections, comments and draft reviews are progressing on schedule and are delivered by the deadlines noted in this WA.

Deliverable Schedule: The schedule and specific expertise requested will be clarified within a TD.

Task 5. Complete Subtasks as Directed by EPA

The specific subtasks under this PWS, identified in Task 4, are described below. Specific clarification will be provided by the EPA WAM through Technical Direction. Technical Direction will be submitted individually for each chemical assessment or project, and the subtasks to be completed will be project-specific (i.e., not all of the subtasks will be completed for each project). EPA estimates that up to 6 work products related to one or more of the 5 primary tasks described below will be required over the period of performance of this PWS.

For some tasks (in particular subtasks 2 and 3 below), the Contractor may be asked to provide their work product using a database format. The database, and any necessary training or guidance on how to populate the database, will be provided to the Contractor by EPA.

1) Evaluation of exposure methods in epidemiological studies. The Contractor shall provide and manage experts to provide guidance and clarification regarding interpretation of exposure measures in epidemiological studies. This will include conducting a review of the reliability and validity of methods used in selected primary source studies, focusing on issues of nondifferential and differential misclassification. A tabular or draft synthesis of conclusions regarding different types of exposure measurement methods may be requested.

2) Study methods evaluation. The Contractor shall provide and manage experts to abstract relevant details pertaining to methods and other details of individual studies to allow for evaluation consistent with the systematic review process. The purpose of this task is to evaluate studies with respect to potential methodological considerations that could affect the interpretation of or confidence in the results by applying a series of specific questions, and documenting study evaluation in tables.

Study methods evaluations should be independent of considerations regarding the direction or magnitude of study results. Study methods evaluations will be performed at an early stage of assessment development, i.e., after identifying the relevant sources of primary data but before developing evidence tables and characterizing hazard associated with chemical exposure. EPA will provide templates or database for the Contractor to use in abstracting study information. The specific details as to what should be abstracted will be determined through consultation with the EPA WAM.

4) Evidence tables. The Contractor shall provide and manage experts to prepare evidence tables that summarize results from epidemiologic studies, consistent with the draft *Handbook for IRIS Assessment Development* and *Elements of an Evidence Table* (Appendix B). The Contractor shall also conduct quality assurance (QA) checks of evidence tables developed by the experts and/or provided by EPA that shall include the following: comparison of table entries to information from the original publication, checking conversions as appropriate (e.g., ppm to mg/m^3), confirming reported exposure ranges and effect measures, and inserting and verifying HERO links. The quality assurance checks should be performed by an expert that was not involved in the initial

development of the table. EPA will provide the most current evidence table template or database for the Contractor to complete the task.

4) Graphical displays. The Contractor shall provide and manage experts to prepare graphical displays of results from epidemiologic studies. Approaches used for categorical exposure data (e.g., forest plots) and approaches used for quantitative data (e.g., representing magnitude of exposure or exposure contrast in relation to magnitude of effect) may be requested; the Contractor will provide expertise to develop or modify graphical displays ass needed. The Contractor shall also conduct quality assurance (QA) checks of the data used to generate graphical displays that shall include the following: comparison of data to information from the original publication, checking conversions as appropriate (e.g., ppm to mg/m^3), and inserting and verifying HERO links. The quality assurance checks should be performed by an expert that was not involved in the initial development of the graphical display.

5) Other epidemiologic support. The Contractor shall provide and manage experts to address other issues that may arise within the context of the review of epidemiologic studies. These issues may pertain to ascertainment of specific outcomes in epidemiology studies, assessment of potential for confounding (e.g., through knowledge of co-exposures in specific workplaces or communities), and other questions regarding bias. This may also include quantitative modeling of epidemiologic data.

Deliverable Schedule: In general, work products shall be delivered in the following formats: tables for subtasks 2, and 3 and text for all remaining subtasks. The deliverable schedule will vary depending on the subtask(s) and chemical, and will depend on the amount and complexity of the information to be evaluated/summarized. The schedule will be clarified within a TD.

Task 6. Revision of Task 5 Deliverables

EPA will submit comments on the Task 5 deliverables. The Contractor shall provide and manage expert epidemiologic expertise to revise those deliverables based on EPA comments. The use of "redline" versions (track changes) of the document will be employed throughout the process. Tasks issued under this WA will be completed when all EPA comments have been considered and addressed, and may require multiple rounds of revision.

Deliverable Schedule: The deliverable schedule will vary depending on the subtask(s) and chemical. Unless otherwise specified in the TD, the Contractor will incorporate EPA comments within 7 days of receipt. The schedule will be clarified within the TD.

V. SCHEDULE OF DELIVERABLES

This schedule and the deliverables dates specified under each Task above may be further clarified using written Technical Direction.

Task	**Schedule** (*all days are elapsed calendar days unless otherwise stated)
1. Develop a Work Plan	In accordance with contract

2. Quality Assurance Project Plan	completed
3. Kick-off Conference Call	completed
4. Manage, Identify and Recruit Expert Epidemiologists	To be clarified in written technical direction.
5. Complete Subtasks as Directed by EPA	To be clarified in written technical direction.
6. Revision of Task 5 Deliverables	To be clarified in written technical direction.

VI. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherently governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO or WAM.

The contractor shall also ensure that work under this work assignment does not contain any apparent or real personal or organizational conflict of interest. The contractor shall certify that none exist at the time the proposal is submitted to EPA. The Contractor shall be responsible for obtaining a conflict of interest certification for any subcontractor services.

VII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall provide regular updates on progress and any issues that need to be resolved to the WAM by telephone or by email. Any technical directions made during informal discussions shall be issued promptly by the EPA WAM in writing (to include email).

VIII. EPA CONTACTS

EPA Work Assignment Manager (WAM)
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MD B-243-01
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EPA Alternate Work Assignment Manager (Alt-WAM)
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Appendix A. Draft IRIS Agenda

Potential Chemicals List	CAS No.
*To be updated as needed	
acetaldehyde	75-07-0
acrylonitrile	107-13-1
ammonia	7664-41-7
arsenic, inorganic	7440-38-2
benzo(a)pyrene	50-32-8
n-butanol	71-36-3
tert-butanol	75-65-0
chlorobenzene	108-90-7
chromium VI	18540-29-9
1,4-dichlorobenzene (1,4-DCB)	106-46-7
diisopropyl ether (DIPE)	108-20-3
dinitrotoluene, technical grade	25321-14-6
ethylbenzene	100-41-4
ethyl tertiary butyl ether (ETBE)	637-92-3
ethylene oxide (inhalation, cancer)	75-21-8
formaldehyde	50-00-0
hexabromocyclododecane (HBCD)	3194-55-6, 25637-99-5
hexahydro-1,3,5-trinitro-1,3,5-triazine (RDX)	121-82-4
isopropanol	67-63-0
Libby amphibole asbestos	1332-21-4
manganese	7439-96-5
mercury, elemental	7439-97-6
methylmercury	22967-92-6
methyl tert-butyl ether (MTBE)	1634-04-4
naphthalene	91-20-3
perfluorooctanoic acid (PFOA)	335-67-1
perfluorooctanesulfonic acid (PFOS)	2795-39-3
phthalates	
butyl benzyl phthalate (BBP)	85-68-7
di-n-butyl phthalate (DBP)	84-74-2
diethyl phthalate (DEP)	84-66-2
di(2-ethylhexyl) phthalate (DEHP)	117-81-7
diisobutyl phthalate (DIBP)	84-69-5
diisododecyl phthalate (DIDP)	40989-56-8
diisononyl phthalate (DINP)	68515-48-0 and 28553-12-0
dipentyl phthalate (DPP)	131-18-0
polychlorinated biphenyls (PCBs) (noncancer)	various
polycyclic aromatic hydrocarbon (PAH) mixtures	various
tert-amyl methyl ether (TAME)	994-05-8
tert-amyl ethyl ether (TAEE)	919-94-8
trimethylbenzenes (1,2,3-,1,2,4-, and 1,3,5-isomers)	526-73-8, 95-63-6, 108-67-8
uranium (natural)	7440-61-1
vanadium, elemental and compounds	various
vanadium pentoxide	1314-62-1

Appendix B. Elements of an Evidence Table (for IRIS Assessments)

Evidence tables are an integral part of IRIS assessments. The first iteration of evidence tables is presented in Stage 1 of the IRIS process (Draft Development) as part of the "Preliminary Package" of public materials. Further iterations or versions of evidence tables are included at later stages of the IRIS process, and may vary depending upon the chemical database and needs of the specific assessment. General elements common to all evidence tables are described below; other elements (including those pertaining to study quality evaluation) may be added to the evidence tables and will vary in content and format to allow for the compilation of the most suitable approach for the respective body of information. These specific elements will be determined by the assessment team with consideration from the scoping and problem formulation process and members from the appropriate workgroup.

I. General elements:

All evidence tables should include the following:

- **Author, year and location of study**: reported in as much detail as possible – country/region, state, city, specific factories, etc.

Hayes et al. (1979) (United States)

- **Study description:** Present study design type, sample size, description of study participants and controls or reference group
    - Study design type: type of study with additional information as follows:
        - Cohort – length of follow up, % lost to follow up
        - Case-control – information on matching if performed
    - Sample size: the number of individuals or study units (e.g., couples, mother-child pairs) in various groups (may include: participation rate and data used in this derivation such as the number of participants recruited, number meeting selection criteria, number in final analysis/analyses, etc.)
    - Study population: This description should include:
        - Any relevant information on how the study population was selected (e.g., factory employment records), including any restrictions or inclusion/exclusions criteria (e.g., only workers with >1 year of job tenure)
        - Information on important demographic characteristics such as distribution of sex, age, and other outcome-specific factors (e.g., for pregnancy outcomes, may want to include parity; for lung cancer, may want to include smoking status)

Case-control study, 56 couples from assisted reproduction center, n=56 control couples (parents), mean age 39 years in both groups.

- **Exposure assessment:** Present how exposure was assessed (e.g., job exposure matrix, air sampling, etc). Also provide some measure of exposure levels (e.g., the mean and range of urinary concentrations of the chemical) for the study population, and/or for each group (e.g., the mean and range among the low and high exposed, or among cases and controls) if available.

- **Outcome assessment**: Present how was the outcome measured/evaluated (e.g., medical record, self-report, physician examination) and the degree that all cases were ascertained.

- **Analysis:** Present statistical methods (including any adjustment variables considered or used in the final analysis), and how results were evaluated. This should include details on how confounding was addressed as well as a description of how statistical significance/precision was evaluated (e.g., use of confidence intervals and/or significance tests).

Proportionate mortality (cancer) ratios, using the U.S. general population to generate expected mortality, adjusted for age, time period of death

- **Results:** Present overall or stratified results as available and appropriate, including any corresponding confidence intervals and/or p-values. If no quantitative results are available, a statement on the results as reported by the author will be provided, making clear that this is the authors' report and not EPA's judgment of results.

Authors note a marked increase in the prevalence of respiratory irritation among exposed workers.

II. Other considerations for generation of evidence tables (not exhaustive):

- **Table Format**: Modifications may be made to the table format depending on the specific database and needs of the assessment. For example, evidence tables may have 2 or 3 columns with the additional column designated for 'Exposure.'
- **Reporting information**: If information is not available, state that it is not reported (e.g. "Outcome: cardiovascular disease (ICD codes not reported)" or "Follow-up time not reported"]
- **Process/Interim Drafts**: It is suggested that the contractor provide an interim draft early in the development process (with about 5 study entries) for review by the epidemiology workgroup. This will allow for early feedback to the contractor prior to the completion of the evidence tables. Further feedback and discussion between the contractor and the epidemiology workgroup is expected throughout the development and evolution of the evidence tables.

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-31

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2016 Base Option Period Number 2	Epidemiologic Support for IRIS

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: A.1,2; B.1,2,3,4,5; C.1; D; and G.1,2

Purpose:
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Period of Performance: From 11/01/2015 To 10/31/2016

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1										
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3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2016	$0.00	0
This Action:	$69,169.00	582
Total:	$69,169.00	582

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated: 11/19/2015	$69,169.00	582
Cumulative Approved:	$69,169.00	582

Work Assignment Manager Name: Amanda Persad (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-9781 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:
Other Agency Official Name (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: William Foster (Signature) Jan 8, 2016 (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-40

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2016	Microbial risk assessment meth
	Base Option Period Number 2	

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	B. 2

Purpose:
- ☒ Work Assignment
- ☐ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 11/01/2015 To 10/31/2016

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SFO (*Max 2*) ☐

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Authorized Work Assignment Ceiling

	Contract Period:	Cost/Fee:	LOE:
	11/01/2013 To 10/31/2016		
This Action:			
Total:			

Work Plan / Cost Estimate Approvals

Contractor WP Dated:		Cost/Fee:	LOE:
Cumulative Approved:		Cost/Fee:	LOE:

Work Assignment Manager Name: Sarah Taft (Signature) (Date)	Branch/Mail Code: Phone Number: 513-596-7037 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 2-40

TITLE: Microbial risk assessment methodology development and application

Specify Section & Paragraph SOW: B2. Support research, development, and application of new risk assessment methods suitable for either conducting or evaluating cumulative risk, microbial risk, mixtures risk, dose-response assessment (including extrapolation to low dose), exposure assessment, and relevant uncertainty analysis.

I. OBJECTIVES

The main objectives of this Work Assignment (WA) are to determine:

- Complete human health risk assessment summary report for *Bacillus anthracis*
- Revise reports and/or papers regarding *Bacillus anthracis* dose-response modeling and physiological characteristics of low-dose *Bacillus anthracis* exposures
- Participate in microbial risk assessment technical working groups covering *Bacillus anthracis* dosimetry and data usability strategies for field sampling data
- Develop exposure pathway assessments for the movement of biologically-contaminated wastewater from the point of use through the wastewater treatment plant to release back into the environment

II. BACKGROUND

The U.S. Environmental Protection Agency's (EPA's) National Homeland Security Research Center (NHSRC) was established to conduct research in support of indoor/outdoor decontamination and water security. Specifically, NHSRC is responsible for assessing potential exposures associated with the intentional or accidental release of hazardous and toxic materials including chemical, biological, and nuclear agents. NHSRC is currently developing tools, technologies, and methods to aid and support this effort. One of the highest priorities of NHSRC is the applications of risk assessment methodologies that can be utilized to support decision making regarding cleanup goals, treatment technology efficacies, detection limits, and waste management options during biological contamination incidents. One exposure scenario of concern is the potential for exposure to possible residual biological contamination after buildings or other areas are cleared for re-entry. Given the potentially unique hazard posed by repeated low-level exposures to *Bacillus anthracis* spores, these assessments are challenged by the identification of appropriate microbial risk assessment models and methodologies.

III. TASKS

Task 1: Workplan

The contractor shall generate a workplan describing how tasks 2-6 shall be performed. The workplan shall include the overall project purpose, scope, and approach. Each task shall be described in detail including the

specifics of the personnel projected to complete each task indicating the level of expertise required, personnel labor hours, timelines to complete each task, projected costs of each task, equipment and supplies required, facilities to be used, specific standard operating procedures (SOPs) (or location of SOPs on-site if considered proprietary business information), standards and controls used for compliance with quality assurance, data analysis and calculations to be utilized, safety considerations, and the risks associated with each task along with proposed mitigations. The workplan shall outline the tasks and subtasks along with timelines projected for completion of each task and task inter-relationships. The contractor shall ensure adherence in the workplan to the existing approved Quality Assurance Project Plan developed under the previous year funding (WA1-40).

Deliverables: Workplan

OPTIONAL Task 2: Exposure Assessment Pathways Analysis Report

If determined by the WA-COR to exercise this task, the contractor shall develop some conceptual models and analysis plan for bio-contaminated wastewater human exposure pathways from the point of collection until the release back into the environment. This would include modeling the wastewater through the wastewater treatment plants and determining if there are any viable exposure pathways of concern given high consequence agent contaminations such as Ebola and *Bacillus anthracis* spores.

Deliverable: Exposure Assessment Pathways Analysis Report

Performance Standard: The contractor shall provide the draft analysis report within 10 months after approval of work plan if determined necessary by the WA-COR.

Task 3: Human Health Risk Assessment Summary for *Bacillus anthracis* Report

The contractor shall revise and respond to any management comments on the summary assessment report of dose-response information and human health risk assessment for *Bacillus anthracis*.

Deliverable: Human health risk assessment summary for Bacillus anthracis report

Performance Standard: The contractor shall provide the draft summary assessment report within 1 months after approval of work plan.

Task 4: Independent Event Modeling and Rabbit Physiological Characterization Papers

The contractor shall revise and respond to comments per journal reviews for at least two journal articles regarding independent event modeling of *Bacillus anthracis* exposures and summarizing rabbit physiological characteristics.

Deliverable: Revised journal articles

Performance Standard: The contractor shall revise journal articles within 1 month after receiving journal comments.

Task 5: Working Group Participation

The contractor shall participate in the National Institute for Mathematical and Biological Synthesis (NIMBioS) and Microbial Data Usability working groups as deemed necessary by the WAM. Participation might include providing expertise for working group publications, collection of technical content and documents, development of methodologies needed to complete working group tasks, and facilitation of the EPA product review processes. Participation will also include travel to at least one working group meeting in Knoxville, TN, for the NIMBioS working group.

Deliverables: Working group participation

Task 6: Communications and Progress Reports

Bi-weekly conference calls shall be conducted between the WAM and the contractor to keep the project team updated on tasks progress and completion as well as any unanticipated issues.

Monthly Reports: Every month, the contractor shall submit reports detailing the overall project status, including a narrative description of the work, preliminary conclusions, and path forward. The monthly report shall provide a concise summary of significant issues, changes in project status, publications, presentations, patents, results of travel, completion of scheduled milestones, project delays and other accomplishments/issues during the reporting period. This report shall also include the financial status at the end of each month (funds received, commitments, obligations, and expenditures) with a graph of the actual and projected obligations and expenditures for the current fiscal year, and new digital pictures relevant to the project.

The contractor shall provide monthly a list of all documents prepared about work done under contract funding to include internal technical reports and presentations, external technical reports and presentations, and responses to requests, whether in written or electronic form, for information from external sources. Copies of such information shall be made available to the WAM on request within two weeks of the request.
The contractor shall also submit combined technical and financial bi-weekly reports through email briefly and concisely updating task progress, changes in project status, significant issues, and financial status.

Outside Presentations of Project Research: Attendance at research meetings to present project results should be limited to the contractor project lead and technical staff on an as needed basis as deemed appropriate by prior consent of WAM. All documents or presentations associated with this project shall be cleared through WAM prior to submission to outside sources as described below. Travel costs associated with this project shall be approved by WAM prior to confirming and registering for meetings.

Reporting Requirements: All contractor generated documents and reports including task reports, interim reports, and task deliverable reports shall be considered draft upon first submission to WAM. WAM shall provide comments back to the contractor within 3 weeks of submission. The contractor shall provide a final version back to WAM with responses and dispositions of comments.

All references cited in submitted reports and deliverables to WAM shall be provided to WAM either as a pdf copy in electronic form on disk or hardcopy.

The contractor shall ensure that all documents prepared under this WA are technically accurate, defensible, free of errors (e.g., data entry, methodology), and editorially correct (e.g., free of typographic and grammatical errors). All supporting information shall be referenced and made available if requested.

The contractor shall be responsible for information and data collection, storage, processing, validation, calculations, reporting, and delivery to WAM. The contractor shall provide document preparation and revision and ensure that the products are responsive, timely, and of high quality to meet the requirements of the Agency.

All documents prepared under these tasks shall respond to the issues identified by WAM, and include supporting references and rationale for the recommendations and conclusions given.

All written information (reports, reviewer comments and meeting reports) shall be prepared using Microsoft Word format. Any spreadsheet or database data shall be in Microsoft Office format compatible with EPA software. The literature resources shall be provided in Adobe Acrobat format (i.e., pdf file) or paper hard copy. The contractor shall provide a CD containing all data and documentation along with three hard copies of the final task deliverable reports and one copy of any references cited in the documents. The documents shall be formatted in 12-point Times New Roman Font and 1-1/2 line spacing.

Deliverables: Bi-weekly conference calls, monthly reports, and periodic meetings.

Performance Standard: The contractor shall participate in bi-weekly conference calls and meetings as needed and submit bi-weekly emails and monthly reports.

IV. DELIVERABLES AND QUALITY ASSURANCE SURVEILLANCE

Task	Deliverable	Performance Standard	Monitoring Method
1	Work Plan	Contractor shall provide the completed Work Plan within 30 days of award	WA-COR shall document whether receipt of Work Plan is timely and acceptable, and provide technical revisions as required
	Revised Work Plan	Contractor shall revise Work Plan if required and submit final Work Plan no more than 30 days after receipt of revisions	WA-COR shall document receipt of revised Work Plan, and ensure that is timely and technically acceptable
Optional Task 2	Exposure Assessment Pathways Analysis	Contractor shall provide the draft Exposure Assessment Pathways Analysis within 10 months after approval of the workplan	WA-COR shall document whether receipt of Analysis is timely and acceptable, and provide technical revisions as required
	Revised Exposure Assessment Pathways Analysis	Contractor shall revise Analysis if required and submit final document no more than 30 days after receipt of revisions	WA-COR shall document receipt of revised Analysis, and ensure that is timely and technically acceptable
3	Human Health Risk Assessment Summary	Contractor shall provide the completed summary report within 3 months after approval of the workplan	WAM shall document whether receipt of summary report document is timely and acceptable, and provide technical revisions as required
	Revised Human Health Risk Assessment Summary	Contractor shall revise summary report if required and submit final document no more than 30 days after receipt of revisions	WAM shall document receipt of revised summary report, and ensure that is timely and technically acceptable

4	Journal Article Revisions	Contractor shall revise journal articles within 1 month after receiving EPA comments	WAM shall document the receipt of journal article revisions, and ensure that they are timely and technically acceptable and provide technical comments as appropriate
5	Working group participation	Contractor shall participate in the working groups as deemed necessary by the WAM	WAM shall document participation in the working groups and identify any issues to be addressed
6	Bi-Weekly Conference Calls	Contractor shall participate in bi-weekly conference calls with the WAM briefly updating project progress	WAM shall participate in these calls to identify any issues to be addressed in the research or future reports
	Monthly Reports	Contractor shall prepare monthly reports as specified in the statement of work	WAM shall document receipt of monthly reports and ensure that these are timely and acceptable
	Meetings with WAM	Contractor shall have periodic meetings with the WAM as needed	WAM shall participate in these meetings and identify any issues to be addressed

VI. INTELLECTUAL PROPERTY

All methods, models, and assays developed by the contractor and/or provided to the contractor under this WA are the intellectual property of the NHSRC and Department of Homeland Security (DHS). All data collected and analyzed under this WA are the intellectual property of the NHSRC and DHS.

Authorship on research presentations associated with this project including, but not limited to, abstracts, posters, PowerPoint presentations, and publications shall be agreed upon prior to submission for consideration by any external organization. Authorship should reflect 1) contribution through project conception and design, 2) data acquisition, 3) data interpretation and analysis, 4) presentation preparation.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS WORK ASSIGNMENT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

1. Formulation of Agency policy
2. Selection of Agency priorities
3. Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of this WA, the contractor should immediately contact the EPA Contracting Officer.

The contractor shall also ensure that work under this WA does not contain any apparent or real personal or organizational conflicts of interest. The contractor shall certify that none exist with its workplan.

VIII. WORK ASSIGNMENT MANAGER (WAM) AND ALTERNATE WAM

WAM:

Sarah Taft, Ph.D.
U.S. EPA OFFICE OF RESEARCH AND DEVELOPMENT
National Homeland Security Research Center
26 W. Martin Luther King Drive (NG-16)
Cincinnati, OH 45268
Work 513/569-7037
Cell 513/288-5460
Taft.Sarah@epa.gov

Alternate WAM:

Eric Rhodes, Ph.D.
U.S. EPA OFFICE OF RESEARCH AND DEVELOPMENT
National Homeland Security Research Center
26 W. Martin Luther King Drive (NG-16)
Cincinnati, OH 45268
Work 513/569-7308
Rhodes.Eric@epa.gov

APPENDIX A

EPA's Quality System Website: http://www.epa.gov/quality

EPA's Requirements and Guidance Documents: http://www.epa.gov/quality/qa_docs.html

EPA's Quality System Website: http://www.epa.gov/quality/qs-docs/r5-final.pdf

In accordance with EPA Order 5260.1 A2, conformance to ANSI/ASQC E4 must be demonstrated by submitting the quality documentation described herein. All Quality documentation shall be submitted to the Government for review. The Government will review and return the quality documentation, with comments, and indicate approval or disapproval. If the quality documentation is not approved, it must be revised to address all comments and shall be resubmitted to the Government for approval. Work involving environmental data collection, generation, use, or reporting shall not commence until the Government has approved the quality documentation. The Quality Assurance Project Plan (QAPP) shall be submitted to the Government at least thirty (30) days prior to the beginning of any environmental data gathering or generation activity in order to allow sufficient time for review and revisions to be completed. After the Government has approved the quality documentation, the Contractor shall also implement it as written and approved by the Government.

NHSRC's Quality System Specifications for Extramural Actions –

These requirements typically pertain to single project efforts. The five specifications are:

(1) a description of the organization's Quality System (QS) and information regarding how this QS is documented, communicated and implemented;

(2) an organizational chart showing the position of the QA function;

(3) delineation of the authority and responsibilities of the QA function;

(4) the background and experience of the QA personnel who will be assigned to the project; and

(5) the organization's general approach for accomplishing the QA specifications in the SOW.

NHSRC QA Requirements/Definitions List

Category Level Designations (determines the level of QA required):

☐ **Category I Project** - applicable to studies performed to generate data used for enforcement activities, litigation, or research project involving human subjects. The QAPP shall address all elements listed in "EPA Requirements for QA Project Plans, EPA QA/R-5.

☐ **Category II Project** - applicable to studies performed to generate data used in support of the development of environmental regulations or standards. The QAPP shall address all elements listed in "EPA Requirements for QA Project Plans, EPA QA/R-5.

[X] **Category III Project** - applicable to projects involving applied research or technology evaluations. The QAPP shall address the applicable sections of "EPA Requirements for QA Project Plans, EPA QA/R-5 as outlined in the **NHSRC's QMP: QAPP** requirements for the specific project type (see below).

[ ] **Category IV Project** - applicable to projects involving basic research or preliminary data gathering activities. The QAPP shall address the applicable sections of "EPA Requirements for QA Project Plans, EPA QA/R-5 as outlined in the **NHSRC's QMP QAPP** requirements for the specific project type (see below).

Project Types:

These outlines of NHSRC's QAPP Requirements for various project types, from Appendix B of the NHSRC QMP (except where otherwise noted), are condensed from typically applicable sections of R-5 (EPA Requirements for QA Project Plans) and are intended to serve as a starting point when preparing a QAPP. These lists and their format may not fit every research scenario and QAPPs must conform to applicable sections of R-5 in a way that fully describes the research plan and appropriate QA and QC measures to ensure that the data are of adequate quality and quantity to fit their intended purpose.

[ ] **Applied Research Project** - pertains to a study performed to generate data to demonstrate the performance of accepted processes or technologies under defined conditions. These studies are often pilot- or field-scale. The QAPP shall address all requirements listed in "QAPP Requirements for Applied Research Projects" from Appendix B of the NHSRC QMP.

[ ] **Basic Research Project** - pertains to a study performed to generate data used to evaluate unproven theories, processes, or technologies. These studies are often bench-scale. The QAPP shall address all requirements listed in "QAPP Requirements for Basic Research Projects" from Appendix B of the NHSRC QMP.

[ ] **Design, Construction, and/or Operation of Environmental Technology Project** - pertains to environmental technology designed, constructed and/or operated by and/or for EPA. The QAPP shall address requirements in the EPA Quality System document "Guidance on Quality Assurance for Environmental Technology Design, Construction, and Operation" G-11, at http://www.epa.gov/quality/QS-docs/g11-final-05.pdf. For additional information, you may refer to Part C of "Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology," ANSI/ASQC E4-1994, American Society for Quality Control, Milwaukee, WI, January 1995.

[ ] **Geospatial Data Quality Assurance Project** - pertains to data collection; data processing and analysis; and data validation of geospatial applications. The QAPP shall address requirements in the EPA Quality System document "Guidance for Geospatial Data Quality Assurance Project Plans" G-5S at http://www.epa.gov/quality/QS-docs/g5g-final-05.pdf.

[ ] **Method Development Project** - pertains to situations where there is no existing standard method, or a standard method needs to be significantly modified for a specific application. The QAPP shall address all requirements listed in "QAPP Requirements for Method Development Projects" from Appendix B of the NHSRC QMP.

[ ] **Model Development Project** - includes all types of mathematical models including static, dynamic, deterministic, stochastic, mechanistic, empirical, etc. The QAPP shall address requirements in the EPA Quality System document "Guidance for Quality Assurance Project Plans for Modeling."

[ ] **Sampling and Analysis Project** - pertains to the collection and analysis of samples with no objectives other than to provide characterization or monitoring information. The QAPP shall address all requirements listed in "QAPP Requirements for Sampling and Analysis Projects" from Appendix B of the NHSRC QMP.

[X] **Secondary Data Project** - pertains to environmental data collected from other sources, by or for EPA, that are used for purposes other than those originally intended. Sources may include: literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. The QAPP shall address all requirements listed in "QAPP Requirements for Secondary Data Projects" from Appendix B of the NHSRC QMP.

[ ] **Software Development and Data Management Project** - pertains to software development, software/hardware systems development, database design and maintenance, data validation and verification systems. The QAPP shall address all requirements listed in "QAPP Requirements for Software Development Projects" from Appendix B of the NHSRC QMP.

Definitions:

Environmental Data - These are any measurement or information that describe environmental processes, location, or conditions; ecological or health effects directly from measurements, produced from software and models, and compiled from other sources such as data bases or the literature. For EPA, environmental data include information collected directly from measurements, produced from software and models, and compiled from other sources such as data bases or literature.

Incremental Funding - Incremental funding is partial funding, no new work.

Quality Assurance (QA) - Quality assurance is a system of management activities to ensure that a process, item, or service is of the type and quality needed by the customer. It deals with setting policy and running an administrative system of management controls that cover planning, implementation, and review of data collection activities and the use of data in decision making. Quality assurance is just one part of a quality system.

Quality Assurance Project Plan (QAPP) - A QAPP is a document that describes the necessary quality assurance, quality control, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria. A QAPP documents project-specific information.

Quality Control (QC) - Quality control is a technical function that includes all the scientific precautions, such as calibrations and duplications, which are needed to acquire data of known and adequate quality.

Quality Management Plan (QMP) - A QMP is a document that describes an organization's/program's quality system in terms of the organizational structure, policy and procedures, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, documenting, and assessing all activities conducted. A QMP documents the overall organization/program, and is primarily applicable to multi-year, multi-project efforts. An organization's/program's QMP shall address all elements listed in the "Requirements for Quality Management Plans" in Appendix B of the NHSRC QMP.

Quality System - A quality system is the means by which an organization manages its quality aspects in a systematic, organized manner and provides a framework for planning, implementing, and assessing work performed by an organization and for carrying out required quality assurance and quality control activities.

R-2. EPA Requirements for Quality Management Plans (EPA/240/B-01/002) March, 2001
http://www.epa.gov/quality/QS-docs/r2-final.pdf.

R-5. EPA Requirements for Quality Management Plans (EPA/240/B-01/002) March, 2001
http://www.epa.gov/quality/QS-docs/r5-final.pdf.

Substantive Change - Substantive change is any change in an activity that may alter the quality of data being used, generated, or gathered.

Technical Lead Person (TLP) - This person is technically responsible for the project. For extramural contract work, the TLP is typically the contracting officer's representative (COR). For intramural work, the TLP is typically the Principal Investigator.

Abbreviations

COR	Contracting Officer's Representative
NHSRC	National Homeland Security Research Center
NRMRL	National Risk Management Research Laboratory
QA ID	Quality Assurance Identification
QAPP	Quality Assurance Project Plan
QS	Quality System
TLP	Technical Lead Person
IAG	Interagency Agreement
QA	Quality Assurance
QAM	Quality Assurance Manager
QMP	Quality Management Plan
SOW	Statement of Work
CRADA	Cooperative Research & Development Agreement

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-40

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2016 Base Option Period Number 2	Microbial risk

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	B. 2

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [X] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2015 To 10/31/2016

Comments:

[ ] Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (Max 2): [ ]

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2016	$0.00	0
This Action:	$93,607.00	596
Total:	$93,607.00	596

Work Plan / Cost Estimate Approvals

Contractor WP Dated: 11/20/2015	Cost/Fee: $93,607.00	LOE: 596
Cumulative Approved:	Cost/Fee: $93,607.00	LOE: 596

Work Assignment Manager Name Sarah Taft (Signature) (Date)	Branch/Mail Code: Phone Number 513-596-7037 FAX Number:
Project Officer Name Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:
Other Agency Official Name (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name William Yates (Signature) 12/24/15 (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107